

K 090355

Section 5

APR 29 2009

Traditional 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	February 11, 2009

Name of the Device

Trade Name:	Opal® Seal
Common Name:	Bracket Adhesive Resin and Tooth Conditioner
Device Classification:	II
Classification Product Code:	DYH

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate devices is: PQ1 (K023042). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095. The Indications for Use have been changed.

Opal® Seal is also very similar to two of our competitor's products namely: Solo Ortho (K990743) manufactured by Sybron Dental Specialties, Inc, 1717 West Collins Ave., Orange, CA 92867 and, LED Pro Seal (K073243) manufactured by Reliance Orthodontic Products, 1540 West Thorndale Ave. Itasca, IL, 60143.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

APR 29 2009

Re: K090355
Trade/Device Name: Opal® Seal
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: April 9, 2009
Received: April 10, 2009

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", with a large, stylized loop at the end.

Susan Runner, D.D.S., MA

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: Opal® Seal

Indications for Use:

Opal® Seal is a light cure primer that is used when bonding orthodontic appliances to etched enamel.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090355

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(Posted November 13, 2003)